



General

Guideline Title

Cerclage for the management of cervical insufficiency.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Cerclage for the management of cervical insufficiency. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2014 Feb. 8 p. (ACOG practice bulletin; no. 142). [50 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on good or consistent scientific evidence (Level A):

- Although women with a current singleton pregnancy, prior spontaneous preterm birth at less than 34 weeks of gestation, and short cervical
 length (less than 25 mm) before 24 weeks of gestation do not meet the diagnostic criteria for cervical insufficiency, available evidence
 suggests that cerclage placement may be effective in this setting. Cerclage is associated with significant decreases in preterm birth outcomes,
 as well as improvements in composite neonatal morbidity and mortality, and may be considered in women with this combination of history
 and ultrasonographic findings.
- Cerclage placement in women without a prior spontaneous preterm birth and a cervical length less than 25 mm detected between 16 weeks and 24 weeks of gestation has not been associated with a significant reduction in preterm birth.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Certain nonsurgical approaches, including activity restriction, bed rest, and pelvic rest have not been proved to be effective for the treatment
 of cervical insufficiency and their use is discouraged.
- The standard transvaginal cerclage methods currently used include modifications of the McDonald and Shirodkar techniques. The superiority of one suture type or surgical technique over another has not been established.
- Cerclage may increase the risk of preterm birth in women with a twin pregnancy and an ultrasonographically detected cervical length less than 25 mm and is not recommended.
- Neither antibiotics nor prophylactic tocolytics have been shown to improve the efficacy of cerclage, regardless of timing or indication.

 A history-indicated cerclage can be considered in a patient with a history of unexplained second trimester delivery in the absence of labor or abruptio placentae.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- Cerclage should be limited to pregnancies in the second trimester before fetal viability has been achieved.
- Transabdominal cervicoisthmic cerclage generally is reserved for patients in whom a cerclage is indicated based on the diagnosis of cervical
 insufficiency but cannot be placed because of anatomical limitations (e.g., after a trachelectomy), or in the case of failed transvaginal cervical
 cerclage procedures that resulted in second-trimester pregnancy loss.
- After clinical examination to rule out uterine activity, or intraamniotic infection, or both, physical examination-indicated cerelage placement (if technically feasible) in patients with singleton gestations who have cervical change of the internal os may be beneficial.
- In patients with no complications, transvaginal McDonald cerelage removal is recommended at 36 to 37 weeks of gestation.
- For patients who elect cesarean delivery at or beyond 39 weeks of gestation, cerclage removal at the time of delivery may be performed; however, the possibility of spontaneous labor between 37 weeks and 39 weeks of gestation must be considered.
- In most cases, removal of a McDonald cerclage in the office setting is appropriate.

Definitions:

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- II-1: Evidence obtained from well-designed controlled trials without randomization.
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendation

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Cervical insufficiency

Note: The term cervical insufficiency is used to describe the inability of the uterine cervix to retain a pregnancy in the absence of the signs and symptoms of clinical contractions, or labor, or both in the second trimester.

Guideline Category

Management

Treatment

Clinical Specialty

Obstetrics and Gynecology

Surgery

Intended Users

Physicians

Guideline Objective(s)

- To provide a review of current evidence of cervical insufficiency, including screening of asymptomatic at-risk women
- To offer guidelines on the use of cerclage for management of cervical insufficiency

Target Population

Women with cervical insufficiency

Note: The diagnosis and management of other cervical issues during pregnancy, such as short cervical length, are discussed more in-depth in other publications of the American College of Obstetricians and Gynecologists (ACOG).

Interventions and Practices Considered

- 1. Transvaginal cerclage placement (modification of the McDonald and Shirodkar techniques)
- 2. Transabdominal cervicoisthmic cerclage (as indicated)
- 3. Cerclage removal (as indicated)

Note: The following interventions were considered but not recommended:

Certain nonsurgical approaches, including activity restriction, bed rest, and pelvic rest

Perioperative antibiotics or prophylactic tocolytics

Ultrasonographic surveillance of cervical length after cerclage placement

Major Outcomes Considered

- Preterm birth outcomes
- Composite neonatal morbidity and mortality

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 2000 and June 2013. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles. When reliable research was not available, expert opinions from obstetrician-gynecologists were used.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force (1989).

- I: Evidence obtained from at least one properly designed randomized controlled trial.
- II-1: Evidence obtained from well-designed controlled trials without randomization.
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Level C recommendations.

Rating Scheme for the Strength of the Recommendations

Levels of Recommendation

Level A—Recommendations are based on good and consistent scientific evidence.

Level B—Recommendations are based on limited or inconsistent scientific evidence.

Level C—Recommendations are based primarily on consensus and expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and subspecialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Cerclage is associated with significant decreases in preterm birth outcomes, as well as improvements in composite neonatal morbidity and mortality.

Potential Harms

- Overall, there is a low risk of complications with cerelage placement. Reported complications include rupture of membranes,
 chorioamnionitis, cervical lacerations, and suture displacement. The incidence of complications varies widely in relation to the timing and
 indications for the cerelage. A cerelage in the presence of membrane rupture or dilation generally is associated with an increased risk of
 complications. Life-threatening complications of uterine rupture and maternal septicemia are extremely rare but have been reported with all
 types of cerelage.
- Compared with transvaginal cerclage, transabdominal cerclage carries a much greater risk of hemorrhage, which can be life threatening, in
 addition to all the other complications associated with abdominal surgery. Furthermore, it generally precludes the performance of uterine
 evacuation or vaginal delivery.
- In some, but not all studies, cerclage retention with preterm premature rupture of membranes (PROM) has been associated with increased rates of neonatal mortality from sepsis, neonatal sepsis, respiratory distress syndrome, and maternal chorioamnionitis.

Qualifying Statements

Qualifying Statements

The information in this guideline is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins—Obstetrics

Composition of Group That Authored the Guideline

This Practice Bulletin was developed by the Committee on Practice Bulletins—Obstetrics with the assistance of Orion Rust, MD and Anthony Odibo, MD, MSCE.

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site

Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

Patient Resources

None available

NGC Status

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